K091533

Garrison
Dental Solutions

AUG 17 2009

510(k) Summary (as required by 21 CFR 807.92(c))

Date Prepared: 5/15/2009

Regulatory Contact for Submission:
Joseph Azary
Orchid Design
80 Shelton Technology Center
Shelton, CT 06484
Tel: (203) 922-0105
Fax: (203) 922-0130
Email: joseph.azary@orchid-orthopedics.com

NOTE: Please send all correspondence regarding this 510(k) submission to Joseph Azary (at the above address).

Manufacturer:
Garrison Dental Solutions
150 Dewitt Lane
Spring Lake, MI 49456
(616) 842-2244
Contact Name: Clarke Reberg

FDA Establishment Registration: 1836088

Name of Device

- Slicks Sectional Matrix Bands
- Slicks Matrix Bands

Classification Name

Dental Matrix Band, Sectional Matrix Band,
Matrix Band (Tofflemire)

Class: Class 1

Medical Specialty (Panel Code): Dental

Product Code: JEP

Regulation Number (CFR Section)
21 CFR 872.4565

Identification of Predicate Device

The predicate devices identified for Slicks Matrix Bands are identified as follows:

- Garrison Composi-Tight Sectional matrix bands – Class 1, 510k exempt
- Waterpik Tofflemire bands - Class 1, 510k exempt
- Young Dental Ho bands - Class 1, 510k exempt
- Danville Sectional Matrix Bands - Class 1, 510k exempt

Description of the Device
Matrix bands are used to retain composite and other restorative materials during dental restorations. In general a matrix band surrounds the tooth and is used to separate the teeth while a composite filling is placed.

The type of band is selected based on the tooth height and restoration type.

The dentist prepares the tooth and places the band on the tooth. A wedge is inserted for optimal contour, gingival seal, and tooth separation.

A ring retainer such as the Composi-Tight 3D Ring or Composi-Tight 3D Thin Tine G Ring is used to hold the band in place.

We believe the wedge and G Ring would be class 1 dental instruments and not subject to 510(k).

The band is removed after the application of composite resin.

The devices are offered in different thicknesses, lengths, and widths to accommodate different sized teeth. Additionally, the device is offered in soft stainless steel and hard stainless steel depending on the preference of the dentist.

The devices are offered in sectional matrix style or standard style (Tofflemire style). The Tofflemire style is a longer thinner band with or without lobes. The choice of style is dependent on the preference of the dentist and the specific condition and size of the patient's teeth.

Intended Use
The device is used in combination with other dental devices to retain composite or amalgam restorative materials during dental restorations.

Comparison to Predicate Device

The main difference between the subject devices and the predicate devices are with regards to the proprietary coating of the subject devices.
Non-Clinical Tests Performed

The device was subjected to and successfully passed biocompatibility testing per ISO 10993, as well as performance testing to measure shear force.

Technological Characteristics
The subject device has passed biocompatibility and shear force testing. These types of devices are typically class 1 exempt from 510(k). We have submitted this 510(k) because the devices are coated with proprietary coating.

Summary
We believe the subject devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2009

Garrison Dental Solutions
C/O Mr. Joseph Azary
Senior Regulatory Consultant
Orchid Design
80 Shelton Technology Center
Shelton, Connecticut 06484

Re: K091533
Trade/Device Name: Slicks Matrix Bands and Sectional Matrix Bands
Regulation Number: 21 CFR 872.4565
Regulation Name: Dental Hand Instrument
Regulatory Class: I
Product Code: JEP
Dated: May 21, 2009
Received: May 26, 2009

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K091533

Device Name: Slicks Matrix Bands & Sectional Matrix Bands

The device is used in combination with other dental devices to retain composite or amalgam restorative materials during dental restorations.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091533